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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|-------------------------------|---------------------|------------------------|
| 10/500,495 | 04/01/2005 | Bipin Chandra Muljibhai Patel | 2003882-0016 | 4500 |
| 24280 | 7590 | 11/13/2009 | | |
| CHOATE, HALL & STEWART LLP | | | | EXAMINER |
| TWO INTERNATIONAL PLACE | | | | PERREIRA, MELISSA JEAN |
| BOSTON, MA 02110 | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 11/13/2009 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

| | | |
|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/500,495 | Applicant(s) PATEL, BIPIN CHANDRA MULJIBHAI |
| | Examiner MELISSA PERREIRA | Art Unit 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 August 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-16,18-49 and 54-83 is/are pending in the application.
 - 4a) Of the above claim(s) 8,9,12-14,21,22,30-49 and 56-83 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-7,10,11,15,16,18-20,23-29,54 and 55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claims and Previous Rejection/Objection Status

1. Claims 1,3-16,18-49 and 54-83 are pending in the application. Claims 8,9,12-14,21,22,30-49 and 56-83 are withdrawn from consideration.
2. The objection to the disclosure is withdrawn.
3. The objections to the instant claims 3 and 4-7,11,15,16,18-20,23-29,54 and 55 are withdrawn.
4. The rejection of claims 1-7,18,20,25-28 and 54 under 35 U.S.C. 102(b) as being anticipated by Ferrari (US 6,107,102) is withdrawn.
5. The rejection of claims 1,4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Loyalka et al. (WO 00/45826) is withdrawn.

Election/Restrictions

6. Applicant asserts that the instant claim 10 reads on the elected species of Boron-containing glass or glass ceramic as the Boron-containing glass or glass ceramic may be in particulate form.
7. The applicant's assertion is accepted and the rejoinder of the instant claim 10 is acknowledged.

Response to Arguments

8. Applicant's arguments filed 8/24/09 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1,3-7,15,16,18-20,23-29,54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari (US 6,107,102) as stated in the office action mailed 5/22/09.

11. Applicant asserts that there is no teaching or suggestion in Ferrari that the biocompatible outer layer is adsorbed onto the neutron capture element.

12. Ferrari teaches that the boron-containing compound may be incorporated into the microdevices comprising a biocompatible layer of the invention either during or after microfabrication. The incorporation of the boron-containing compound into a biocompatible does not exclude adsorption to the biocompatible layer. Ferrari further teaches that the incorporation of agents, such as therapeutic agents, other functionality-enhancing agent into the microdevices includes conjugation to the device, incorporation into matrices (e.g. polymer matrices), etc. (column 12, lines 35+). Therefore, at the time of the invention it would have been obvious to one ordinarily skilled in the art that the boron-containing compound (i.e. functionality-enhancing agent) may be incorporated, conjugated into the matrices (e.g. polymer matrices) of the microdevice, including adsorption.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1,3-6,10,11 and 18-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Day et al. (US 4,889,707) in views of Glajch et al. (US 6,455,024 B1).

15. Day et al. (US 4,889,707) discloses insoluble radioactive microspheres comprising a biodegradable or biologically compatible glass material containing a beta radiation emitting radioisotope chemically dissolved therein (column 4, lines 34-52). The microspheres are initially nonradioactive, upon being subjected to an effective amount of neutron radiation, will produce a beta radiation emitting radioisotope (column 4, lines 44-52). The biodegradable glass material may be lithium aluminoborate, lithium silicate, etc. and the radioisotope chemically dissolved in and distributed substantially uniformly throughout the glass material may be samarium-153, rhenium-188, yttrium-90, etc. (column 5, lines 10-37). The homogeneous batch powders (i.e. samarium doped lithium silicate glass) may be melted to form the desired glass composition (column 7, lines 10+). The glass microspheres are activated by subjecting them to an effective amount of neutron irradiation which will produce a beta radiation emitting radioisotope, the amount depending on the particular isotope of these elements that has been chemically dissolved and uniformly distributed throughout the glass material (column 8,

lines 26-38). Day et al. does not disclose of nanoparticles or a biocompatible outer layer.

16. Glajch et al. (US 6,455,024 B1) discloses particles which are in a glass state and have an average particle diameter of about 0.05 microns (abstract; column 1, lines 8-16). The particles are comprised of aluminas, silicas, phosphates, etc and radionuclides, such as ⁹⁰Y, ¹⁸⁸Re, ¹⁵³Sm which may be coated, adsorbed or incorporated into the matrix of the particle (abstract; column 2, lines 38-60; column 3, lines 22-45; column 5, lines 62+). The radionuclide is activated by neutron bombardment after or prior to formation of the particle (column 4, lines 62+). The particles may be coated with organic materials, such as PVP to enhance their stability, to prevent aggregation, to alter their tissue distribution in the body and their elimination from the body, to reduce toxicity or enhance effectiveness, to control the dissolution rate of soluble particles and to control the permeation of water and other substances into and out of the particle matrix, among other uses (column 2, lines 61+; column 4, lines 15-24; column 10, lines 23+).

17. At the time of the invention it would have been obvious to one ordinarily skilled in the art to prepare insoluble radioactive nanoparticles in a glass state. The glass materials of both disclosures are analogous and include silicates and therefore one would have a reasonable expectation of success for preparing nanoparticles of the particles of Day et al.

18. Also, at the time of the invention it would have been obvious to one skilled in the art to coat the particles of Day et al. with an organic materials/biocompatible outer layer,

such as PVP to enhance their stability, to prevent aggregation, to alter their tissue distribution in the body and their elimination from the body, to reduce toxicity or enhance effectiveness, to control the dissolution rate of soluble particles and to control the permeation of water and other substances into and out of the particle matrix, among other uses (Glajch et al. column 2, lines 61+; column 4, lines 15-24; column 10, lines 23+).

Conclusion

19. No claims are allowed at this time.
20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618